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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
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March 23, 1999

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 99-11

Chul Lee, Owner
Sam Uk Fish Cake Company
1112 South 344th Street, Number 304
Federal Way, Washington 98003

WARNING LETTER

Dear Mr. Lee:

On December 4, 1998, an FDA investigator and an FDA analyst conducted an inspection of your firm located at 1112-S. 344th Street, Number 304, Federal Way, Washington. At the conclusion of the inspection, you were presented with a Form FDA 483, listing serious deviations from Title 21 of the Code of Federal Regulations 21 CFR Part 123 – Fish and Fishery Products (HACCP Regulation). By virtue of these deficiencies, the vacuum-packaged, refrigerated, ready-to-eat fish cakes processed at your facility are adulterated within the meaning of Section 402(a)(4) of the Food Drug and Cosmetic Act (the Act) and 21 CFR Part 123.

Specifically, the following deficiencies were found related to fried fish cakes and steamed fish cakes that are sold refrigerated, in vacuum packages, and ready-to-eat.

1. Your firm does not have and has not implemented a HACCP plan in accordance with 21 CFR Part 123.6(b) which requires seafood processors to have and implement a written HACCP plan whenever one or more food safety hazards are identified. During our inspection, we identified *Clostridium botulinum* growth and toxin formation, *Staphylococcus aureus* growth and toxin formation at the cooling step, and survival of pathogens through cooking as potential hazards which your firm should be controlling. In addition, we believe there is some potential for recontamination with pathogens such as *Salmonella* and *Listeria monocytogenes.*

   In our *Fish & Fisheries Products Hazards & Controls Guide: Second Edition*, Chapter 13, we recommend that firms intending to vacuum pack their seafood products have their

processing methods evaluated by a competent process authority to establish the effectiveness of the process in preventing the growth of *Clostridium botulinum*. This would be especially important for products such as yours, which are ready-to-eat or brown and serve.

Measures that you may apply to vacuum packaged fish products to prevent the formation of *Clostridium botulinum* toxin during distribution and storage include:

a. freezing the product, and labeling that the product must be thawed under refrigeration immediately before use;
b. retorting to commercial sterility;
c. pasteurizing to eliminate *Clostridium botulinum* types E and non-proteolytic B and F;
d. reducing the pH;
e. controlling the water activity; or
f. using a combination of factors, e.g., control of acidity and water activity.

2. You were not monitoring four of eight elements of sanitation, including safety of water, protection from adulteration, proper labeling, use and storage of toxic compounds, and exclusion of pests.

   21 CFR Part 123.11(b) requires that you monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with good manufacturing practices (GMP). 21 CFR Part 123.11(c) requires that you maintain sanitation control records that document the monitoring of sanitation and any corrections that are made as a result of the monitoring.

   The FDA acknowledges receipt of your letter dated July 8, 1998, and further acknowledges that you have taken some steps to correct the problems with your firm's HACCP system. However, we are gravely concerned that you remain seriously out of compliance with 21 CFR Part 123.

The above violations are not meant to be an all-inclusive list of deficiencies in your plant. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products comply with applicable statues enforced by the FDA. You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Pertinent sections of the Act and the Regulations are enclosed for your review. Your reply relating to these concerns should be addressed to the Food and Drug

Administration, Attention: Janelle K. Main, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421.

Sincerely,

Roger L. Lowell
District Director

3 Enclosures:
Form FDA 483 Inspectional Observations
21 CFR Part 123
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: WSDA with disclosure statement